Roche - Investor Update

Investor Update

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Basel, 20 November 2006

NeoRecormon receives positive opinion in Europe for convenient once weekly treatment of anaemia in cancer patients with solid tumours

Roche announced today that it has received a positive recommendation from the European Committee for Medicinal Products for Human Use (CHMP) for a convenient once weekly subcutaneous dose of its anti-anaemia agent NeoRecormon 30,000 IU in solid cancers. This represents an important amendment as cancer patients on chemotherapy currently are recommended to receive NeoRecormon three times per week according to the label.

The NeoRecormon 30,000 IU once weekly regimen will allow physicians and patients to benefit from a simple dosing schedule which helps to provide optimal care without adding to the burden of cancer treatment.

Final marketing approval is still to be awaited from the European Commission. The opinion is based on a submission dossier which included data from the BRAVE (BReast cancer - Anaemia and the Value of Erythropoietin) study, which was conducted in women with metastatic breast cancer receiving chemotherapy. 1,2

About NeoRecormon

NeoRecormon (epoetin beta) has been prescribed for over 16 years for the treatment of anaemia in patients with chronic kidney disease and cancer. Treating anaemia increases red blood cell numbers and oxygen levels allowing the body to function effectively, which improves patients' quality of life and may reduce morbidity and mortality. NeoRecormon is one of Roche's leading biotechnology achievements and market leader in the countries in which it is sold. More than 1 million patient years of experience have been gained with the product around the world and this widespread use has confirmed both the benefits NeoRecormon brings to patients and established its well defined safety record. Physicians can choose to prescribe NeoRecormon via intravenous or convenient subcutaneous routes of administration.

About Anaemia

Anaemia affects up to 95% of cancer patients receiving chemotherapy.³ It can develop as a result of the cancer itself or as a consequence of its treatment. For most patients anaemia manifests itself as an extreme and overwhelming fatigue that adds to the burden of their illness. Anaemia and this fatigue have a significant impact on quality of life and long-term outcomes for patients with cancer. Even though there are effective treatments, anaemia often remains under-diagnosed and under-treated. In Europe approximately 60% (two out of every three) cancer patients do not receive treatment for anaemia.5

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and

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diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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- 5 Ludwig H et al. Eur J Cancer 2004; 40: 2293-2306.
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Roche



Basel, 20 November 2006

Mircera: first drug to correct anaemia in all chronic kidney disease patients with a simple twice-monthly dosing schedule

Results from two Roche studies show for the first time that chronic kidney disease patients on dialysis as well as those not on dialysis who need correction of renal anaemia, can be successfully treated with Mircera on a simple twice monthly dosing schedule – an option that does not exist today. Mircera was shown to be as effective as existing agents in correcting renal anaemia while reducing the dosing frequency 2 to 6-fold of these drugs. Two phase III trials demonstrating these findings were presented at the 39th annual meeting of the American Society of Nephrology in San Diego, USA.

"There is no doubt that Mircera is very effective at correcting anaemia," said Dr. Iain Macdougall, Consultant Nephrologist and Honorary Senior Lecturer at King's College Hospital in London and an investigator in the ARCTOS trial. "We were pleased to see a smooth rise in, and stable control of, haemoglobin at these initial dosing intervals of twice a month. It is important with new patients being treated for the first time to feel confident in carefully managing their rise in haemoglobin."

Mircera the first and only Continuous Erythropoietin Receptor Activator (C.E.R.A.), is a new drug under development for the treatment of anaemia in patients with CKD. Roche filed applications with regulatory authorities in the European Union and the United States in April this year seeking approval for use of the treatment in anaemia associated with CKD in patients on dialysis and not on dialysis.

About the ARCTOS and AMICUS studies

The primary objective of these two correction studies, ARCTOS and AMICUS, was to examine the effectiveness of intravenous (IV) and subcutaneous (SC) Mircera at extended administration

intervals in correcting anaemia and maintaining Hb levels in treatment-naive patients with CKD either on dialysis or not. The studies used epoetin alfa/beta or darbepoetin alfa as comparator agents in a non-inferiority designⁱ.

In the first study, ARCTOS (Administration of C.E.R.A. in CKD Patients to Treat Anaemia with a Twice Monthly Schedule), 324 patients with CKD who were not on dialysis were randomized to either Mircera once every two weeks or darbepoetin alfa once a week subcutaneously. The response rate was 97.5% for Mircera and 96.3% for darbepoetin. After 28 weeks, patients who responded to Mircera were randomized to continue treatment twice a month or monthly with the same dose; patients on darbepoetin remained on once-weekly treatment. In a post-hoc analysis, only 12.4% of patients on Mircera had one Hb value greater than 13 g/dL during the first 8 weeks while 33.5% of patients on darbepoetin alfa exceeded this upper limit.

"Effective elevation and predictable control of haemoglobin are key to managing renal anaemia, improving physical functioning and reducing the risk of complications," said Robert Provenzano, Chief, Division of Nephrology, Hypertension & Transplantation, St. John Hospital & Medical Center in Detroit, Michigan and an investigator with one of the US-based clinical trial sites for ARCTOS. "These results show Mircera may provide doctors with a way to manage anaemia with less frequent dosing."

The second study, AMICUS (C.E.R.A. AdMinistered Intravenously for Anaemia Correction and SUStained Maintenance in Dialysis), examined intravenous Mircera once every two weeks against the controls, epoetin alfa or epoetin beta 1-3x/wk, in 181 dialysis patients. 93.3% of patients on Mircera achieved target Hb levels versus 91.3% for epoetin alfa or beta, indicating Mircera is effective in maintaining Hb levels with a single dose every two weeks.

"These findings demonstrate Mircera's clear ability to effectively and safely correct anaemia in patients on dialysis along with offering a convenience for patients and medical staff with extended twice monthly dosing intervals," said Marian Klinger, MD, Medical University, Wroclaw, Poland and an investigator in the AMICUS study.

About Renal Anaemia

Renal anaemia is a common and debilitating complication of CKD that's characterized by a low concentration of haemoglobin (Hb) in the blood. Inadequate Hb levels deprive the body's tissues of oxygen and can lead to serious cardiovascular complications and even death if left untreated. Treatment guidelines recommend specific ranges that they suggest doctors target – achieving an

 $Hb \ge 11$ g/dL and maintaining Hb levels in the optimal range as excessive Hb correction is not associated with additional benefit and has been associated with increased risk. Most CKD patients receive chronic anti-anaemia treatment as often as 52-156 times a year because existing agents for renal anaemia are short-acting, requiring more frequent administration to keep Hb levels within guideline ranges. Today's results, presented at the 39th Annual Meeting of the American Society of Nephrology, indicate Mircera can successfully correct Hb with twice monthly dosing.

About the phase III clinical trial program

The Mircera phase III clinical program was the largest clinical development program ever conducted for the treatment of renal anaemia. The program consisted of two initiation/correction and four conversion/maintenance studies of both IV and SC Mircera at extended administration intervals. Initial findings from the phase III 'maintenance studies,' were presented at the European Renal Association-European Dialysis and Transplant Association congress in July 2006. These results showed that for the first time, patients with CKD on dialysis treated with short-acting and frequently administered epoetin anti-anaemia drugs can be successfully and directly switched to a once-monthly treatment, resulting in stable Hb levels.

About Mircera

Roche's innovative investigational anti-anaemia agent is the first Continuous Erythropoietin Receptor Activator (C.E.R.A.), which is a new class of drugs. Its activity at the receptor sites involved in stimulating red blood cell production is different from that observed with traditional epoetin drugs. The distinct molecular interaction of Mircera is believed to play an important role in providing targeted, stable and sustained control of anaemia.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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¹ Non-inferiority studies are required to gain registration for a medicine when treatments already exist to manage the condition in question as placebo controlled studies are no longer ethical. In this situation, regulatory authorities ask for studies showing the new medicine to be at least as effective to existing agents with a similar safety profile.

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Investor Update



Basel, 17 November 2006



FDA approves Herceptin for the adjuvant treatment of HER2-positive node-positive breast cancer

Dear Investor,

Please find attached a Genentech news release announcing that the U.S. Food and Drug Administration (FDA) approved Herceptin (Trastuzumab), as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel, for the adjuvant treatment of HER2-positive node-positive breast cancer. Adjuvant therapy is given to women with early-stage (localized) breast cancer who have had initial treatment – surgery with or without radiation therapy – with the goal of reducing the risk of cancer recurrence and/or the occurrence of metastatic disease.

Please do not hesitate to contact us if you have any further questions.

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FDA APPROVES HERCEPTIN® FOR THE ADJUVANT TREATMENT OF **HER2-POSITIVE NODE-POSITIVE BREAST CANCER**

-- Herceptin Significantly Reduced the Risk of Breast Cancer Recurrence by 52 Percent in Pivotal Studies --

-- Only Targeted Biologic Therapy Approved for Use in Adjuvant and Metastatic HER2-positive Breast Cancer --

SOUTH SAN FRANCISCO, Calif. -- Nov. 16, 2006 -- Genentech, Inc. (NYSE: DNA) announced today that the U.S. Food and Drug Administration (FDA) approved Herceptin® (Trastuzumab), as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel, for the adjuvant treatment of HER2-positive node-positive breast cancer. Adjuvant therapy is given to women with early-stage (localized) breast cancer who have had initial treatment - surgery with or without radiation therapy - with the goal of reducing the risk of cancer recurrence and/or the occurrence of metastatic disease.

The FDA approval was based on data from an interim joint analysis of more than 3,500 patients enrolled in two Phase III clinical trials. These results showed that the addition of Herceptin to standard adjuvant therapy significantly reduced the risk of breast cancer recurrence, the primary endpoint of the studies, by 52 percent (or a hazard ratio of 0.48) in women with HER2-positive breast cancer, compared to those patients who received standard adjuvant therapy alone.

"The results of the joint analysis show that, for women with early-stage HER2-positive breast cancer, the addition of Herceptin to chemotherapy reduces the relative risk of breast cancer recurrence by approximately half, which translates into fewer women dying from one of the most aggressive types of breast cancer," said Edward Romond, M.D., Professor of Medicine, Division of Hematology/Oncology at the University of Kentucky. "This is the largest improvement in outcome for any group of women with breast cancer in 25 years."

"Our work with Herceptin exemplifies our commitment to developing the right drug for the right patient. We designed Herceptin for the approximately 25 percent of women whose breast cancers overexpress HER2 because we believed that we could make a significant impact for these patients battling a very aggressive, difficult-to-treat disease," said Susan Desmond-Hellmann, M.D., M.P.H., Genentech's president, product development. "These adjuvant studies showed that, in women with HER2-positive lymph node-positive breast cancer, Herceptin reduces the risk of developing metastatic disease, which could benefit thousands of lives worldwide each year."

"This approval also highlights a first step in a major initiative to conduct studies of Genentech targeted therapies in earlier stages of disease where they have the potential to have the greatest impact," added Desmond-Hellmann.

After three-and-a-half years in the study, 87 percent of women treated with Herceptin plus chemotherapy were disease free, compared to 71 percent of women treated with chemotherapy alone. A survival analysis conducted after patients had been followed for a median of 24 months showed a 33 percent reduction in the risk of death (based on a hazard ratio of 0.67), which is equivalent to a 49 percent improvement in overall survival.

Each study had an independent external Data Monitoring Committee (DMC) that reviewed data from the studies, including cardiac safety data, on a regular basis. According to the investigators, serious or life-threatening (and in rare cases, fatal) cardiac events, most commonly congestive heart failure (weakening of the heart muscle), occurred approximately 3 to 4 percent more often in the Herceptin plus standard therapy arms than in the standard therapy alone arms. Other adverse events reported in both studies included dyspnea and interstitial pneumonitis, which occurred at a rate of less than 1 percent.

"Today's approval is wonderful news for women with early-stage HER2-positive breast cancer and another significant milestone in the Herceptin story," said Fran Visco, president of the National Breast Cancer Coalition. "Thanks to the thousands of breast cancer patients, clinical investigators, the FDA, Genentech and advocates, who have all played critical roles in Herceptin's development, we now have a treatment option that represents a major advance for women with HER2-positive breast cancer before the disease has metastasized. We look

forward to continuing our collaboration with Genentech on future Herceptin research."

Additional Background on the Joint Analysis Studies

The two Phase III trials were sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and conducted by a network of researchers led by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the North Central Cancer Treatment Group (NCCTG), in collaboration with the Cancer and Leukemia Group B, the Eastern Cooperative Oncology Group and the Southwest Oncology Group.

These randomized, controlled trials studied four cycles of doxorubicin (adriamycin) and cyclophosphamide followed by paclitaxel, either every three weeks or weekly for 12 weeks, compared with the same regimen plus 52 weeks of Herceptin beginning with the first dose of paclitaxel.

The joint analysis results were first presented at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO) in May 2005 and subsequently published in *The New England Journal of Medicine* (NEJM) in October 2005.

About Herceptin

Herceptin is a targeted therapeutic antibody treatment for women who have tumors that overexpress the human epidermal growth factor receptor 2 (HER2) protein. HER2-positive breast cancer is an especially aggressive form of the disease that affects approximately one-fourth of women with breast cancer. Research has shown that women with HER2-positive breast cancer have a greater likelihood of recurrence, poorer prognosis and decreased survival compared to women with HER2-negative breast cancer. Special testing is required to identify women who have HER2-positive breast cancer and who may be candidates for treatment with Herceptin.

Herceptin is the only targeted biologic therapy approved for treatment of HER2-positive breast cancer in the adjuvant and metastatic settings. Herceptin first received FDA approval in September 1998 for use in women with metastatic breast cancer. In this setting, it is indicated for treatment of patients both as a first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy.

In clinical trials of HER2-positive metastatic breast cancer patients, Herceptin in

combination with chemotherapy (paclitaxel) was the first anti-HER2 agent to demonstrate an improvement in survival in a Phase III trial. In December 2001, Genentech received FDA approval to include, in the product label, data that showed an improved median overall survival for women with HER2-positive metastatic breast cancer treated initially with Herceptin and chemotherapy, compared to chemotherapy alone (median 25.1 months compared to 20.3 months).

Herceptin Safety Profile

Herceptin administration can result in left ventricular dysfunction and congestive heart failure (CHF). The incidence and severity of left ventricular cardiac dysfunction/CHF were highest in patients who received Herceptin concurrently with anthracycline-containing chemotherapy regimens.

Herceptin should be discontinued in patients receiving adjuvant therapy for breast cancer who develop a clinically significant decrease in left ventricular function. In patients with metastatic breast cancer who develop a clinically significant decrease in left ventricular function, discontinuation of Herceptin should strongly be considered.

Serious infusion reactions and pulmonary toxicity have occurred; rarely these have been fatal. Discontinuation of Herceptin should be strongly considered for infusion reactions manifesting as anaphylaxis, angioedema, pneumonitis, or acute respiratory distress syndrome.

Exacerbation of chemotherapy-induced neutropenia has also occurred.

The most common adverse reactions associated with Herceptin use were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea (shortness of breath), rash, neutropenia (decrease in the number of neutrophils, a type of white blood cell), anemia, and myalgia (muscle pain).

About Breast Cancer

According to the American Cancer Society, 212,920 women in the United States will be diagnosed with breast cancer in 2006, and 40,970 will die from the disease. Excluding skin cancer, breast cancer is the most common form of cancer among women and the second-leading cancer killer among women, after lung cancer. The chance of a woman having invasive breast cancer some time during her life is about 1 in 8.

The chance of dying from breast cancer is about 1 in 33. Breast cancer death rates are going down. This decline is probably the result of finding the cancer earlier and improved treatment.

Genentech's Commitment to Patient Access

Genentech is committed to assisting eligible patients in accessing our therapies for approved indications, regardless of their ability to pay. Although Genentech's products are covered by most government and private insurance, Genentech established the Genentech® Access to Care Foundation (GATCF) in 1990 for its marketed products. GATCF donates product to eligible patients in the United States who are uninsured or deemed uninsured due to payor denial, except for Pulmozyme® (dornase alfa, recombinant), which is covered by the Genentech Endowment for Cystic Fibrosis. In 2005 alone, GATCF supported over 18,000 patients by providing approximately \$200 million of free product. In addition, Genentech recently doubled to \$50 million its donation to several independent public charities that provide financial assistance to eligible patients who cannot access needed medical treatment due to co-pay costs. To learn more about potential financial assistance options, patients can speak with an Alternative Funding Specialist from Genentech's Single Point of Contact (SPOC) group by calling 866-724-9394 or visiting http://www.SPOConline.com.

About Genentech BioOncology

Genentech is committed to changing the way cancer is treated by establishing a broad oncology portfolio of innovative, targeted therapies with the goal of improving patients' lives. The company is the leading provider of anti-tumor therapeutics in the United States.

Genentech is conducting clinical development programs for Rituxan® (Rituximab), Herceptin® (Trastuzumab), Avastin® (bevacizumab), and Tarceva® (erlotinib), and markets all four products in the United States, either alone (Avastin and Herceptin) or with Biogen Idec Inc. (Rituxan) or OSI Pharmaceuticals, Inc. (Tarceva). For sale outside of the United States, Genentech has licensed Rituxan, Herceptin, and Avastin to Roche, and OSI Pharmaceuticals has licensed Tarceva to Roche.

The company has a robust pipeline of potential oncology therapies with a focus on four key areas: angiogenesis, apoptosis (i.e., programmed cell death), the HER pathway, and B-

cell biology. An investigational antibody directed at the HER pathway is currently in Phase II trials. In early development, are a small molecule directed at the hedgehog pathway and an investigational agent targeting apoptosis.

Founded 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products and licenses several additional products to other companies. The company has headquarters in South San Francisco, Calif., and is listed on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit http://www.gene.com.

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For full prescribing information, including Boxed WARNINGS for Herceptin, please call 800-821-8590 or visit http://www.gene.com.



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Basel, 16 November 2006

The Salzburg Festival and Roche launch the "Continents..." cultural project Ground-breaking partnership encourages access to innovation in music and science for young people

The Salzburg Festival and Roche are to establish a joint cultural project in the area of contemporary music: The new "Continents..." series will invite audiences at the Salzburg Festival on a journey of discovery through the compositional and aesthetic universe of prominent 20th/21st century composers. This collaboration between Roche and the Salzburg Festival will primarily allow European university and college students to attend contemporary music events in Salzburg, and will attempt to uncover the link between innovation in music and art on the one hand and science on the other. In addition, new communication channels will be opened up, giving both the Salzburg Festival and Roche access to interesting new target groups.

Roche is supporting the "Continents..." project at the Salzburg Festival as part of its commitment to contemporary music and art and is making a substantial financial contribution that will allow a ticket price reduction of more than 30% for the next five years. Roche will also coordinate the marketing of "Continents..." at university and college level via its own networks and channels and will run a project specifically aimed at upcoming young scientists, "Roche Continents — Youth! Arts! Science!". As part of this project, up to 100 students of science, music and the arts from around the globe will be given the opportunity to spend a week in Salzburg exploring various topics from the world of art and science in a series of workshops.

Speaking of the project, Franz B. Humer, Board Chairman and CEO of Roche, said: "I am absolutely delighted that Roche is able to collaborate with the Salzburg Festival in launching 'Continents...'. This new partnership is a good match with our other successful projects in the area of innovative contemporary music: Roche Commissions in Switzerland and the United States, and the international Roche'n'Jazz initiative. Through this new project we aim to encourage young

people to explore different aspects of contemporary music and in this way to indirectly heighten their fascination with innovation in general, and scientific innovation in particular."

Helga Rabl-Stadler, President of the Salzburg Festival comments: "Thanks to Roche, the Festival and Markus Hinterhäuser, who came up with the idea for 'Continents...' and who will be responsible for programming the concerts, can pick up where the successful 'Zeitfluss' tradition of the 1990s left off. From 2007, there will once again be a 'festival within the festival'. With its generous five-year commitment, Roche has secured the budget for an important piece of programming. But Roche also stands to gain from its sponsorship of the project. A critical confrontation with New Music can give people the courage to change various aspects of their lives. Young scientists will recognise that art is the real arena in which ideas are being developed today."

"Continents..." will get underway in summer 2007 with the works of the Italian transcendental composer Giacinto Scelsi. Scelsi (1905-1988) was one of the leading exponents of 20th century music. The poetry of Scelsi's music – and this is particularly true of his solo pieces, originally for piano, but later for a whole variety of instruments – is derived from its supreme concentration on a single note and the timbral variations which slowly unfold and evolve. In 2008, the "Continents..." series will focus on Salvatore Sciarrino and in 2009 on Jannis Xanakis.

About Roche

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Further information

- Roche cultural sponsorship: <u>www.roche.com/sus_csoc-resp-arts</u>
- Salzburg Festival www.salzburgfestival.at

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